



October 28, 1999

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99D-2638, Compliance Policy Guide 615.115 Use of Medicated Feeds for Minor Species

The National Aquaculture Association (NAA), representing a diversity of US aquaculture interests with over 2000 members, endorses the draft Compliance Policy Guide 615.115 entitled "Use of Medicated Feeds for Minor Species."

United States aquaculture and the welfare of farm raised aquatic animals is significantly compromised by the lack of approved drugs. Contrary to aquaculturists in most other countries, US aquaculture is limited to two antibacterials, one parasiticide, one anesthetic and one reproductive aid. The proposed CPG would provide some limited flexibility to the veterinary profession to use approved medicated feeds in an extra-label manner. The limited scope of the CPG will prevent any significant expansion in antibacterial agent usage by the aquaculture industry. We note that the same policy was practiced prior to the 1994 Animal Medicinal Drug Use Clarification Act. During that time, there was only limited use of approved medicated feeds for non-labeled uses. We believe only limited use occurred because of the practical limitations of cross-species feed acceptance.

Review of recent publications regarding international aquaculture practices (referenced below) suggests the current use of antibiotics in medicated feeds internationally is of low risk to humans. Since antibiotic use in United States aquaculture is even more restrictive and limited than internationally, we suggest implementation of the draft CPG will not alter the already safe use of antibiotics or other drugs by the US aquaculture industry.

We appreciate FDA efforts on behalf of the US aquaculture industry.

Sincerely,

Jesse Chapell
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President

99D-2638

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References: P.Smith, M.P. Hiney, and O.B. Samuelson. 1994. Bacterial resistance to antimicrobial agents used in fish farming: a critical evaluation of method and meaning. *Ann. Review of Fish Diseases* 4: 273-313.

D. Alderman and T.S. Hastings. 1998. Antibiotic use in aquaculture: development of antibiotic resistance- potential for consumer health risk. *Int. J. Food Sci and Technology*. 33(2): 139-155.



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